From the Southern Association for Vascular Surgery

Maldeployment of the TAG thoracic endograft

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The TAG thoracic endograft is a commercially available device used for endovascular repair of thoracic aneurysms. It has a single-action deployment mechanism, similar to its abdominal counterpart, consisting of an expanded polytetrafluoroethylene string, which is used to constrain the self-expanding stent graft within an integral external expanded polytetrafluoroethylene corset. This report describes two cases of deployment failure of the TAG device and the bailout techniques used to correct the problem and complete the procedure. In one case, this complication resulted in a devastating intraoperative stroke that led to the death of the patient. Although this is an extremely rare occurrence, the rapid recognition of the problem and ability to correct it by using catheter-based techniques are important during endovascular treatment of thoracic aortic diseases using the TAG device. (J Vasc Surg 2007;46:1032-5.)

The TAG (W.L. Gore, Flagstaff, Ariz) device is a commercially available endograft for treatment of descending thoracic aortic aneurysms. The system was Food and Drug Administration–approved in January 2005.[1] Since then, more than 1000 US physicians have been trained in its use, and more than 10,000 implantations have been performed worldwide. It has a one-step (Sim-Pull) deployment mechanism (Fig 1) similar to the abdominal Excluder (W.L. Gore). This report describes two cases of failed deployment of the TAG device and the salvage techniques used to complete the procedure.

The TAG device is a nontapered, tubular stent graft constructed of sinusoidal nitinol stent rings embedded in layers of expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene graft material. It is delivered through a separate 20F to 24F 35-cm introducer sheath with a Keller-Timmerman pinch valve to prevent contact of the bare device against the rough calcific surface of the abdominal aorta and iliac arteries, which could risk premature deployment.

Similar to the abdominal Excluder, the TAG device is deployed by using a single-step mechanism (Sim-Pull). A single ePTFE string exits out of the distal end of the delivery catheter through a modified Tuohy-Borst valve. This string binds an ePTFE corset by using a proprietary stitching pattern along a longitudinal seam that runs the full length of the device and constrains the TAG device. By pulling on the string, the seam is opened, thus deploying the self-expanding nitinol stent graft in situ. There are additional ePTFE string loops at the ends that connect to the delivery catheter to prevent excessive rotation of the constrained device around the central hypotube. The primary string also releases these terminal control loops. The delivery catheter has radiopaque "olives" that bookend and longitudinally fix the constrained device on to the hypotube. Unlike the abdominal Excluder, however, the TAG device starts deploying in the middle and proceeds outward in a bidirectional manner. The putative benefits of this deployment include avoiding a windsock effect and effectively halving the deployment time per given device length. After control angiography, the delivery catheter is positioned and stabilized, and the Sim-Pull string is pulled with a single, smooth motion under live fluoroscopy. The string is removed intact and should be without evidence of fracture or fraying; the delivery catheter is then carefully retracted back through the stent graft.

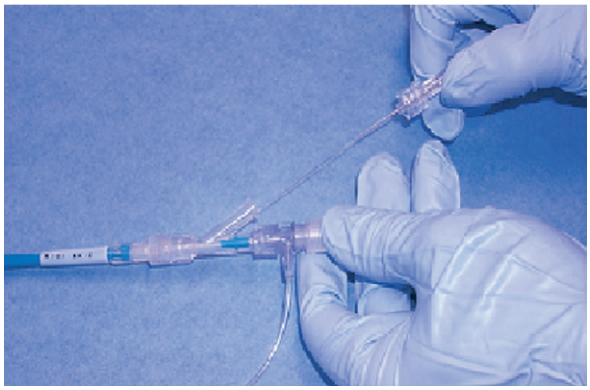

Fig 1. The Sim-Pull string that is used to deploy the TAG device. A single strand is used to stitch the seam and exits out of the distal end of the delivery catheter.

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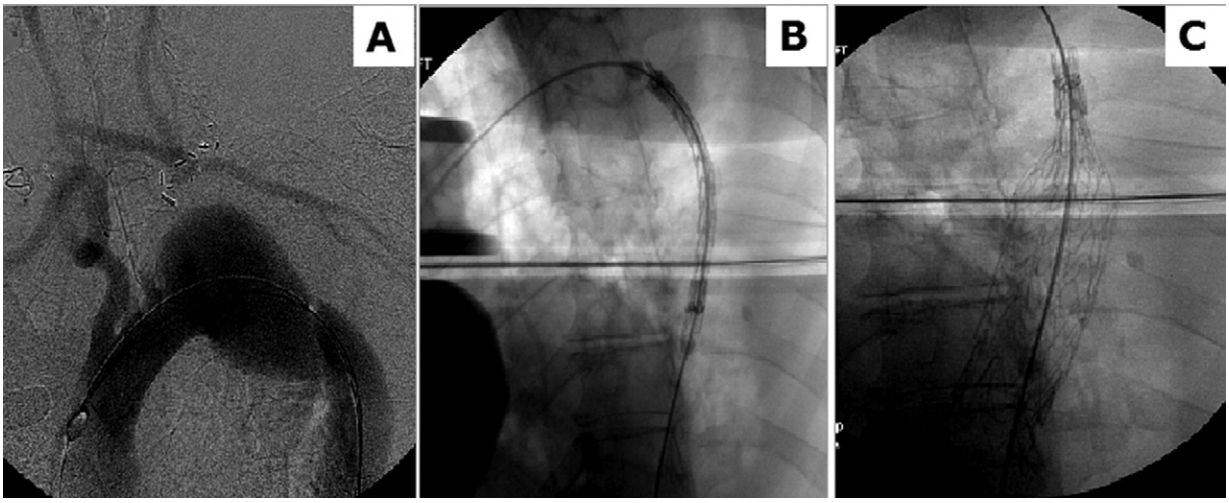

Fig 2. A, Initial aortogram showing the aneurysm and the extra-anatomic revascularization of the arch vessels. **B,** The 31 × 100 mm TAG device being delivered to the proximal arch. **C,** The proximal end of the TAG device remains undeployed.

CASE REPORTS

Case 1. The patient was a 79-year-old woman who had a 7.5-cm distal arch thoracic aortic aneurysm. Preoperative evaluation included a chest-abdomen-pelvis computed tomographic angiogram and a carotid duplex examination. There was no evidence of any significant occlusive disease of the common carotid arteries or the bifurcation. She underwent a right carotid-to-left subclavian artery bypass with reimplantation of the left carotid artery to gain an additional proximal landing zone, with a plan to perform a TAG stent graft repair as a single stage under general anesthesia. A 22F 35-cm introducer sheath was advanced to the proximal abdominal aorta, and a 31 × 100 mm device was inserted and positioned in the transverse arch after control angiography. The deployment string was pulled, but the proximal end of the device failed to deploy. (Fig 2) The string came out intact without any evidence of a break, and there was no resistance or other tactile cues that indicated any irregularity. Initial attempts to gently tease the leading olive tip through the undeployed proximal end resulted in caudal movement of the device into the mid descending thoracic aorta and partial intussusception of the proximal end into the endograft. The entire delivery catheter was essentially trapped by the nosecone, which could not be retracted through the undeployed device, and the patient had a period of near-total thoracic aortic occlusion.

The stent graft rode freely over the delivery catheter, and the distal olive was used to push out the intussusception and "drag" the stent graft back up to the proximal descending thoracic aorta. Through the contralateral femoral access, an 0.018-inch guidewire was introduced into the open distal end of the endograft and passed through the space between the constrained end of the device and the hypotube. A 4-mm balloon was used to initially dilate the opening, which allowed exchange to an 0.035-inch guidewire and serial dilation up to an 8-mm angioplasty balloon. There was tight waisting of the balloon until at approximately 12 atm, when the constraining loop was broken and the end was fully opened. The delivery catheter was removed, and two additional TAG devices were required to complete the procedure. As the device introducer sheath was being withdrawn, the iliac artery became disrupted, thus necessitating temporary balloon control, retroperitoneal exploration, and an iliofemoral bypass. The entire procedure took approximately 5 hours, with a fluoroscopy time of 67 minutes, 160 mL of contrast, and blood loss of 2000 mL. After surgery, the patient did not wake up from anesthesia, and a brain magnetic resonance image revealed multiple bihemispheric infarcts in the anterior and posterior circulations and watershed territories. A computed tomographic angiogram showed that the stent grafts were well positioned, the aneurysm was completely excluded without an endoleak, and all the bypass grafts were patent. Despite usual supportive measures, she did not to recover any meaningful neurologic function and eventually died on postoperative day 68. Although the exact etiology of the patient's stroke could not be ascertained, the likely causes include thromboemboli from the extensive manipulation of the TAG device in the arch after it failed to deploy and the transient intraoperative hypotension from the iliac disruption.

Case 2. A 69-year-old man had a 6.1-cm type III thoracoabdominal aortic aneurysm and underwent a staged hybrid procedure involving a retrograde ilioceliac and ilio–superior mesenteric artery bypasses (stage 1) followed by a TAG stent graft (stage 2) repair 9 days later. The patient had end-stage renal failure that necessitated chronic hemodialysis and therefore did not require revascularization of the renal arteries. Under general anesthesia, a 24F 35-cm sheath was introduced through the left femoral artery but was able to be advanced only into the distal aorta as a result of the marginal size and atherosclerotic disease of the iliac artery. A 37 × 200 mm TAG device was inserted through this sheath to the proximal descending thoracic aorta without significant difficulty. The deployment cord was pulled, but the device failed to deploy at its proximal end. Through a contralateral femoral access, an 0.014-inch guidewire was used to initially traverse the constrained sec-

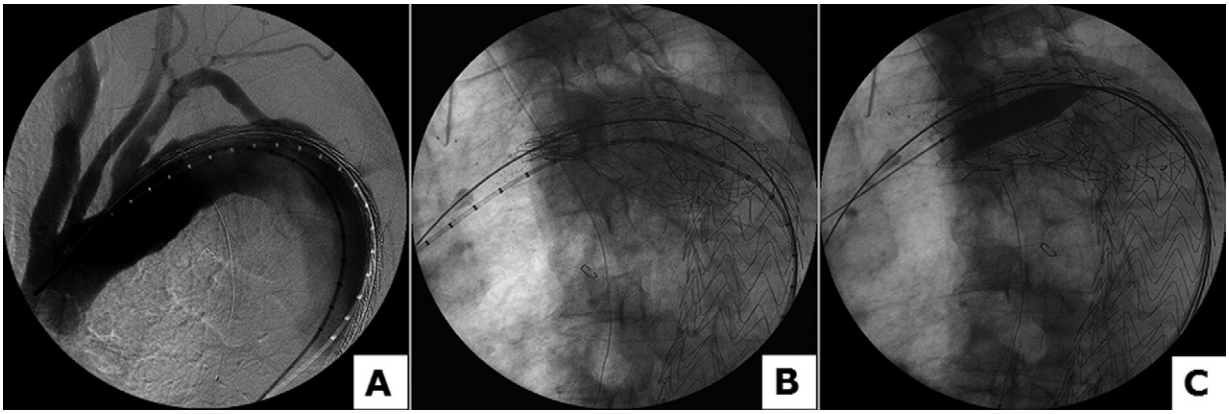

Fig 3. A, Undeployed TAG device in the proximal descending thoracic aorta. **B,** The proximal end of the device remains constrained. **C,** A 12-mm balloon is used to break the loop and fully deploy the device.

Fig 4. The second device also failed to deploy completely within the first device, which also did not deploy.

tion. Serial angioplasties including a 12-mm balloon inflated up to 8 atm were required to break the ePTFE loop (Fig 3). Remarkably, a second 37 × 200 mm device, which was used to extend the repair distally, again failed to deploy in a similar manner, and the same salvage maneuvers had to be repeated (Fig 4). Comparison of the stock numbers of the two devices did not indicate that they came from the same batch. The procedure was completed satisfactorily in 134 minutes, with 59 minutes of fluoroscopy, 270 mL of contrast, and 700 mL of blood loss. The patient had an uneventful hospital course and was discharged on postoperative day 3 without further complications. At 14 months, the stent graft remained intact, and the aneurysm had decreased by 4 mm with no endoleak.

DISCUSSION

The two deployment failures reported in this article represent a failure mode unique to this particular device. To our knowledge, this complication has not been reported in the literature. Failure modes of aortic endografts can be broadly categorized into acute and late types. In the acute category, almost all of the device-related failures are directly or indirectly related to deployment and/or anatomic issues. These can involve mechanical problems, as demonstrated in these two cases, or technical issues due to operator error or case selection.[2-4] Although material or manufacturing issues such as large needle holes, mispackaging, or mislabeling may also occur, these have largely been avoided with rigorous quality control. Late failures, conversely, are typically related to stent fractures and fabric erosions or progressive degenerative changes in the native artery.[5,6]

The TAG device has appealed to operators because of its simplicity of deployment. However, this apparent simplicity at the user end is gained at the expense of a complex stitching pattern and series of interlocking loops that are the Achilles heel of this deployment mechanism. Despite the high tensile strength of the ePTFE material, each centimeter of the seam and stitch can represent a failure point from a break in the string. This is in contrast to the conventional pin-pull-unsheathe mechanism of deployment used by most self-expanding stent platforms, which also has its disadvantages, especially in the thoracic aorta. Regardless of what method is used, it is important to have some built-in fail-safe mechanism so that if the primary mode fails, the delivery catheter can be deconstructed in some manner to complete the process once the device is partially deployed.

The causes of the device failures in these two cases remain unsolved. As previously mentioned, the deployment strings in all three devices were carefully inspected, and there was no evidence of any breaks. It is interesting that the proximal end of the stent graft failed to deploy in both cases. Clearly, the reverse situation in which the distal end remained constrained would have posed a greater

technical difficulty. In the latter instance, it would have created a true windsock, which could have pushed the entire device distally until it wedged itself in a narrow segment of the thoracoabdominal aorta, thus potentially occluding vital branch vessels. Furthermore, the technique described in this report of balloon fracture of the constraining loop would have been nearly impossible from a femoral approach and would have required brachial access to gain entry through the open proximal end of the stent graft. In the worst-case scenario, in which both ends fail to deploy, it would likely necessitate open conversion.

In conclusion, reliable deployment of an endograft is critical to the safety of the patient and the success of the procedure. Knowledge of bailout techniques, which are unique to the failure modes of individual devices, is essential to the routine use of these devices. Nowhere is this truer than for aortic endografts in the thoracic aorta. These salvage maneuvers may require both endovascular and surgical techniques, and this serves as a cogent argument for a multidisciplinary approach to the treatment of these diseases.

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